

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 27 JUN 2005

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Applicant's or agent's file reference PU4927WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/38483	International filing date (day/month/year) 04 December 2003 (04.12.2003)	Priority date (day/month/year) 18 December 2002 (18.12.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 11/00, 15/00, 16/00 and US Cl.: 128/200.11, 200.12, 200.13, 200.14, 200.23, 203.12, 203.15, 203.21, 203.22		
Applicant GLAXO GROUP LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 11 June 2004 (11.06.2004)	Date of completion of this report 27 April 2005 (27.04.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Teena Mitchell <i>Teena Mitchell</i> Telephone No. (571) 272-3700

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/38483

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.☒ the description:

pages 1-13 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the claims:

pages 14-18 as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the drawings:

pages 1-17 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☐ the sequence listing part of the description:

pages NONE as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages NONE☐ the claims, Nos. NONE☐ the drawings, sheets/fig NONE5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims 14-26, 29-34

YES

Claims 1-4, 6-13, 27, 28

NO

Inventive Step (IS)

Claims NONE

YES

Claims 1-34

NO

Industrial Applicability (IA)

Claims 1-34

YES

Claims NONE

NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-4, 6-13, 27, and 28 lack novelty under PCT Article 33(2) as being anticipated by Nohl (6,390,088).

With respect to claim 1, Nohl discloses a container (2) having the pharmaceutical formulation comprising at least one medicament present therein; and a mouthpiece (6) configured for oral engagement, the mouthpiece having an inner surface and an outer surface; wherein the outer surface of the mouthpiece contains at least one longitudinally-extending groove (7) disuniformity such that when the patient orally engages the mouthpiece (6) at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient (Figs. 2, 3).

With respect to claim 2, Nohl discloses wherein the at least one longitudinally-extending disuniformity is selected from the group consisting of at least one protrusion, at least one indentation, at least one opening in the outer surface of the mouthpiece (6, Figs. 1, 2).

With respect to claim 3, Nohl discloses wherein at least one longitudinally-extending disuniformity comprises a plurality of protrusions (Figs. 2, 3).

With respect to claim 6, Nohl discloses wherein the protrusions are present throughout the outer surface of the mouthpiece (Figs. 2, 3).

With respect to claim 7, Nohl discloses wherein at least one protrusion is present as one protrusion (Figs. 2, 3).

With respect to claim 8, Nohl discloses wherein the at least one longitudinally-extending disuniformity comprises a plurality of indentations (Figs. 2, 3).

With respect to claim 9, Nohl discloses wherein the plurality of indentations comprise two indentations present opposite to each other along sides of the mouthpiece (Figs. 2, 3).

With respect to claim 10, Nohl discloses wherein the longitudinally-extending disuniformity is present as at least one opening (Figs. 2, 3).

With respect to claim 11, Nohl discloses wherein the at least one opening comprises a plurality of openings (Figs. 2, 3).

With respect to claim 12, Nohl discloses wherein the plurality of openings comprises two openings each present to each other on opposing sides of the mouthpiece (Figs. 2, 3).

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

With respect to claim 13, Nohl discloses wherein the pharmaceutical formulation comprises at least one medicament (Col. 1, lines 8-19).

With respect to claim 27, note rejection of claims 1, 2, 8 and Col. 1, lines 8-19.

With respect to claim 28, Nohl discloses activating the inhaler to deliver the at least one medicament to the patient (Col. 1, lines 8-19).

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over Nohl (6,390,088).

With respect to claim 5, Nohl does not specifically show the plurality of protrusions present opposite to each other along respective side of the mouthpiece. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have protrusions located opposite to each other along respective sides of the mouthpiece, since it has been held that rearranging of parts of an invention involves only routine skill in the art.

Claims 14-26 and 29-34 lack an inventive step under PCT Article 33(3) as being obvious over Nohl (6,390,088) in view of Rand (6,474,331).

With respect to claims 14-26 and 29-34 and the specific medicament Nohl does not disclose the specifics. Rand in an inhaler teaches the limitations of the above claims, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the specific medicament as claimed based on the teachings of Rand because such medicaments are well known in the respiratory art (Col. 9, lines 40-67 and Col. 10, lines 1-20).

----- NEW CITATIONS -----